

REMARKS/ARGUMENTS

Claims 1-54 were pending in the instant application prior to amendment. Claims 25-26 have been cancelled, and various claims as discussed above have been amended. The claims pending at this time are therefore claims 1-24 and 27-54. Claims 10-24 and 27-54 have been withdrawn from consideration on the basis that they are drawn to a non-elected invention, and claims 1-9 therefore stand rejected on various grounds. The objections and rejections are addressed in the appropriate sections below. Applicant specifically reserves the right to pursue the subject matter of original claim 1 as well as claims 25 and 26 in a continuing application claiming the benefit of the present application.

The present application is believed to be in condition for allowance.

35 U.S.C. § 112, Second Paragraph

Claims 1-9 stand rejected under 35 U.S.C. § 112, second paragraph for allegedly being indefinite as failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Office Action states that:

“The claims are confusing and unclear by the preamble of claim 1 requiring treating a blood product containing a nucleic acid-containing pathogen to be inactivated, and not inactivating the pathogen in the steps carried out. The steps of claim 1 require removing free psoralen and low molecular weight psoralen photoproducts from a blood product, and nowhere recite a step of inactivating a nucleic acid-containing pathogen as required in the claim preamble.”

“The claims are further confusing in that the meaning and scope of “psoralen photoproducts” is uncertain.”

Applicants have amended claim 1 to more particularly and distinctly claim the invention. The presently-claimed subject matter finds support at, *inter alia*: page 61 lines 17-20 (para. 303 in

the published application) and page 62 lines 10-12 (para. 305) (a psoralen and a photoproduct each qualifies as a low molecular weight psoralen compound); p. 81 lines 13-16 (para. 380) (removal of a psoralen from a blood product such as platelets, plasma and serum).

Applicants believe that all the grounds of indefiniteness have been adequately addressed in order to overcome the rejections. Therefore, it is respectfully requested that these rejections under §112, second paragraph, be withdrawn.

35 U.S.C. § 103(a)

Claims 1-9, 25 and 26 stand rejected under 35 U.S.C. § 103 as being allegedly obvious over Wollowitz et al., in view of Tsyurupa et al. and Davankov et al. Applicants respectfully traverse the rejection. Applicants have cancelled claims 25-26, rendering the rejection moot as to these claims. As noted earlier, Applicants specifically reserve the right to pursue the subject matter of claims 25-26 in a continuing application.

In order for two or more references in combination to render a claimed invention obvious, there must be some motivation to combine selected features discussed in those references. There has to be some specific motivation that directs a person of ordinary skill in a particular field to apply what secondary references teach, such as some problem discussed in the field or a specific improvement noted as desirable in that field that the reference indicates to one of ordinary skill should be incorporated into the subject matter of the first reference.

Claims 1-9 were rejected on the basis that “[i]t would have been obvious to substitute for the Amberlite XAD-4 adsorbent resin of Wollowitz et al., the hypercrosslinked polystyrene-divinylbenzene copolymer taught by Tsyurupa et al. and Davankov et al. for the expected advantage of the hypercrosslinked copolymer providing exceptional adsorption capacity. Since both Amberlite XAD-4 and the hypercrosslinked copolymer are polystyrene-divinylbenzene copolymers and are essentially the same except for hypercrosslinking, it would have been expected that the hypercrosslinked copolymer would provide the sorption function of Amberlite XAD-4 required by

Wollowitz et al. of removing free psoralen compounds from treated blood or synthetic blood media.”

The rejection of pending claims 1-9 is apparently based on the premise that one of ordinary skill in any field would find it obvious to try using a polystyrene-divinylbenzene hypercrosslinked resin in place of a polystyrene-divinylbenzene resin that the person was already using in that field, based on the statements in Tsyurupa et al. that the hypercrosslinked resin has exceptionally high adsorption capacity. As the Examiner can appreciate, this is not a standard of obviousness that courts have sanctioned.

For claimed subject matter to be obvious, there must be some clear teaching in the field that motivates a person of ordinary skill in the relevant field to go beyond what a primary reference teaches and apply what secondary references teach to the subject matter of the primary reference. That motivation does not exist in this instance. “The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process *should* be carried out”¹

There is no notation in Wollowitz et al. of any deficiency in adsorbing the psoralen intended to be adsorbed. In fact, even the present application notes the particular effectiveness of certain resins such as XAD-4 in removing a low molecular weight psoralen compound. Page 72 lines 13-17 (para. 340), for instance, indicates that residual level of psoralen in a blood product that was processed using XAD-4 was much better than the residual psoralen level for other Amberlite products. Wollowitz et al. therefore provides no basis for one of ordinary skill in the field of blood-borne nucleic acid-containing pathogen inactivation and purification to seek a resin with higher adsorption capacity.

¹ In re. Dow Chemical Co., 837 F.2d 469 (Fed. Cir. 1988) (emphasis added). See also In re. Vaeck, 947 F.2d 488 (Fed. Cir. 1991).

The Tsyurupa et al. reference also does not provide one of ordinary skill in the field of blood-borne nucleic acid-containing pathogen inactivation with a reason to adopt the claimed method. There is nothing in this reference that indicates it necessarily should be applied to the Wollowitz et al. teaching. As noted above, Wollowitz et al. does not discuss any deficiency in adsorption capacity to be overcome, and thus a broad statement in the Tsyurupa et al. reference to increased adsorption capacity does not in view of the teaching of both references indicate that one of ordinary skill *should* provide a hypercrosslinked resin in Wollowitz' process.

In view of the above, the references provide no motivation for one of ordinary skill in the art to modify a method as discussed in Wollowitz et al. in the manner suggested in the Office Action. Claims 1-9 are therefore patentable over the cited references, and Applicants request withdrawal of the rejection.

35 U.S.C. § 102(e)

Claims 25 and 26 were rejected under 35 U.S.C. § 102(e) as being anticipated by Wollowitz et al. (U.S. Patent No. 5,593,823). Applicants have cancelled claims 25 and 26, rendering the rejection moot. Applicants specifically reserve the right to pursue the claimed subject matter in a continuing application claiming the benefit of the present application.

Provisional obviousness-type double patenting rejection

Claims 1-9, 25 and 26 stand provisionally rejected under the judicially created doctrine of double patenting to U.S. Patent Application No. 09/972,323 or 10/011,202. Applicants note the provisional nature of the rejection but respectfully traverse the rejection. Applicants are in the process of filing a notice of appeal and appeal brief for each of copending 09/972,323 and 10/011,202, and therefore Applicants expect that these applications will not issue prior to issuance of a patent for the presently-claimed invention. In view of this, Applicants submit that the provisional obviousness-type double-patenting rejection will not in fact lead to a nonprovisional rejection.



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In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

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